Priority

Applicants acknowledge that the Examiner has established the priority date for the present application as December 3, 1999. Enclosed herewith is a new signed Supplemental Declaration reflecting the amended priority date.

Rejections Under 35 U.S.C. § 112, first paragraph (enablement)

Claims 19-22 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter, which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention as claimed. Specifically, the Action states that, while the specification is enabling for stimulating an immune response in a subject, it allegedly does not reasonably provide enablement for stimulating a protective immune response of said polypeptide in said subject. Applicants respectfully traverse this ground of rejection.

Applicants submit that the presently pending claims are directed to methods of stimulating an immune response in a subject or a biological sample using at least an immunogenic portion of a polypeptide sequence selected from sequences at least 98% identical to SEQ ID NO:190. It is submitted that the present specification provides ample guidance on how one of skill in the relevant art would make and/or use the polypeptides of the present invention to stimulate an immune response specific for a Chlamydia antigen in a subject or a biological sample.

Applicants have demonstrated utility of the methods of the present invention both *in vitro* and *in vivo*. Upon reviewing Examples 1-7, 9, and 13, one of skill in the relevant art would be able to obtain a biological sample, for example peripheral blood mononuclear cells (PBMCs), and use the polypeptides of the present *e.g.,* SEQ ID NO:190, to stimulate an immune response. These Examples describe obtaining PBMCs from both symptomatic and asymptomatic subjects, incubating these PBMCs with the polypeptides of the present invention in order to stimulate an immune response, and detecting stimulated T cells based on their production of IFN-gamma in response to specific stimulation with a Chlamydia antigen. Indeed Applicants submit that without stimulating an immune response in these samples, it would not be

possible to use the assays described throughout the specification, *e.g.,* IFN-gamma ELISPOT (described for example on page 113, lines 24-25), proliferation assays (an example of which is described on page 124, line 23 through page 125, line 6), IFN-gamma ELISA assays (page 110, lines 1 through 15), and CTL assays (an example of which is described on page 116, lines 1 through 9) to detect Chlamydia-specific T cells. In fact, one of skill in the relevant art would appreciate that the immunological assays described throughout the specification rely on the stimulation of T cells using polypeptides, such as SEQ ID NO:190 and their subsequent production of IFN-gamma in order to detect these Chlamydia-specific T cells. Applicants therefore submit, that one of skill in the art is enabled, in light of the present specification and the level of skill in the art, to use SEQ ID NO:190 as well as immunogenic portions and variants thereof to stimulate an immune response in a biological sample or subject.

The Action also alleges that the specification, while enabling for stimulating an immune response in a subject, as presently claimed, does not reasonably provide enablement for stimulating a protective immune response in a subject. The Action alleges that although claim 19 does not require a particular therapeutic use, the claims implicitly state the intended use of the method in light of the specification. Applicants respectfully traverse this ground of rejection.

Applicants submit that the very nature of the data presented in the present specification clearly demonstrate that immune responses to SEQ ID NO:190 are generated *in vivo*, *e.g.,* the detection of T cells which are specifically immunoreactive when stimulated with SEQ ID NO:190. Further, Applicants have described in Examples 5 and 9 how one of skill in the art can use Chlamydia specific polypeptides in a mouse to generate Chlamydia-specific T cells responses. Further, the specification further demonstrates that these T cells provide protective immunity as measure by the decreased presence of inflammation of the genital track in animals exposed to a Chlamydia antigen versus controls. Therefore, Applicants submit, that one of skill in the art, based on the level of disclosure in the present specification, including the presence of working examples which specifically describe not only the generation of immune response to Chlamydia antigens, but additionally, the protection provided by these immune responses, would be enabled to use the methods of the present invention to stimulate an immune response in a subject, a fact on which the Action concedes. Applicants respectfully submit that this ground of rejection has been overcome and request that the Examiner withdraw the same.

Rejection Under 35 U.S.C § 112, second paragraph

Claims 19-22 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention. More specifically, the Action alleges that the claims are vague and indefinite because claim 19 calls for stimulating an immune response, however, neither the subject of the stimulation nor the subject of the response have been identified in the claims. Applicants respectfully traverse this ground f rejection.

However, for purposes of clarity, Applicants have amended claim 19 to recite, in part "A method for stimulating an immune response in a subject", and have added new claim 23 to recite "A method for stimulating an immune response in a biological sample". Applicants respectfully submit that the subject of the stimulation and the subject of the response have been identified, *i.e.,* either a subject or a biological sample. Reconsideration and withdrawal of this rejection is respectfully requested.

The Action further alleges that the claims are vague and indefinite as claim 20 recites that the polypeptide of (b) is capable of stimulating T cells that are stimulated by SEQ ID NO:190. The Action alleges that it is unclear whether stimulating T cells with SEQ ID NO:190 before the polypeptide administration is a pre-requisite for the capability of the polypeptide in stimulating an immune response. Applicants respectfully traverse this ground of rejection. However, for the purposes of expediting prosecution, and without acquiescing to this ground of rejection Applicants have elected to cancel claim 20 at this time. Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102(a)

Claims 19-22 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by PCT Publication No. WO 99/17741. More specifically, the Examiner alleges that PCT Application No. WO 99/17741 teaches a polypeptide sequence that is 97.2% identical to SEQ ID NO:190, and methods of using the polypeptide in a physiologically acceptable carrier for inducing a protective immune response in an animal. The Examiner states that WO 99/17741 further teaches that adjuvants could be included in the composition to enhance the effectiveness

of vaccination, and therefore WO 99/17741 allegedly anticipates the instant claims. Applicants respectfully traverse this ground of rejection. However, solely for the purposes of expediting prosecution and not acquiescence, Applicants have amended claim 19, in part, to recite "(b) a sequence 98% identical to the polypeptide of SEQ ID NO190". Applicants submit that support for this amendment can be found, for example on page 59, lines 25 through 28. Reconsideration and withdrawal of this rejection is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"

All of the claims remaining in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

Ajay Bhatia et al.

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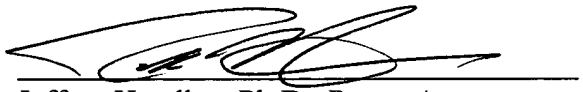

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Paragraph beginning at page 1, line 5, has been rewritten as follows:

REFERENCE TO RELATED APPLICATIONS

This application is related to U.S. Patent Application No. 09/620,412, filed July 20, 2000; 09/598,419, filed June 20, 2000; U.S. Patent Application No. 09/556,877, filed April 19, 2000; U.S. Patent Application No. 09/454,684, filed December 3, 1999; ~~U.S. Patent Application No. 09/426,571, filed October 22, 1999; U.S. Patent Application No. 09/410,568, filed October 1, 1999; U.S. Patent Application No. 09/288,594, filed April 8, 1999; U.S. Patent Application No. 09/208,277, filed December 8, 1998 (granted);~~ each a CIP of the previous application and pending unless otherwise noted, and each incorporated in its entirety herein.

In the Claims:

Claim 20 has been canceled.

Claim 19 has been amended as follows:

New claim 23 has been added.

19. (Amended) A method for stimulating an immune response in a subject, said method comprising administering a composition comprising an isolated polypeptide comprising an immunogenic portion of a polypeptide sequence selected from the group consisting of (a) the polypeptide of SEQ ID NO:190; and (b) a sequence ~~95~~98% identical to the polypeptide of SEQ ID NO:190, and thereby stimulating an immune response to Chlamydia.

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